REMARKS

This amendment responds to the Office Action which was mailed on January 9, 2007. In the specification, a substitute specification has been submitted herewith in which the reference numerals which appeared on the left hand side of all pages of the original specification have been removed as requested. No other changes were made to the specification as originally filed. In the claims, Claims 15 and 16 have been amended. In light of the amendments and the remark set forth below it is respectfully submitted that Claims 15 and 16 are in condition for allowance. Applicant requests a favorable reconsideration of this application in light of the amendment and the remarks set forth below which constitute a full and complete response to the outstanding Office Action.

Claims 15 and 16 were objected to because the SEQ ID NOS 1-6 had been put in brackets. The claims have now been amended to delete the brackets.

Claims 15 and 16 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More particularly, Claim 15 was considered indefinite for reciting "contacting a nucleic acid sequence forming at least a portion of nucleic acid encoding *staphylococcal* enterotoxin A." This claim has now been amended to clarify the language. In addition, the term "sufficient" was also rejected as indefinite, and it too has now been deleted from the claim by the amendment.

Claim 15 was rejected under 35 U.S.C. §103(a) as being unpatentable over the publications of Letertre et al. in light of O'Connell et al., and further in view of Borst et al. Letertre and O'Connell were relied on to teach the method steps of real-time fluorescence PCR, while Borst was relied on to teach primers "100% identical to SEQ ID NO: 3 and SEQ

ID NO: 5." It is respectfully submitted that this argument is untenable and should be withdrawn because Borst does not actually teach primers identical to those disclosed and claimed by applicant.

More specifically, the primer sequences taught in Borst are simply not designed for real-time PCR and differ from applicant's primers in several respects. First, the primer sequences taught in Borst amplify a sequence of 272 base pairs in length. Target sequences that are optimal for real-time fluorogenic PCR are in the range of 50-150 base pairs in length. Accordingly, applicant's primers amplify sequences of 101 and 99 base pairs in length. In addition, Borst simply does not teach primers with sequences identical to those claimed by applicant. Borst teaches an upstream primer of 5' AGCATACTGCAAGTGAAGTTG 3'and a downstream primer of 5' TTGTTGTCAACGTTAGGG 3'. These sequences are not matches with the primer sequences claimed by applicant in Claim 15. It is believed that any match found to applicant's sequences probably resulted from the fact that the entire sequence of Accession L22565 was referred to in the Borst publication. L22565 comprises the entire sequence of accession for the upstream region of the *sea* gene. Therefore, it may include as part of the entire sequence those potions identified by applicant as SEQ ID NO: 3 and SEQ ID NO: 5, but that does not constitute a teaching of those specific primer sequences which are only a small part (20 or 21 bases) of the L22565 Accession. Furthermore, the majority of SEQ IDS which are claimed and disclosed by applicant are not included in the L22565 Accession at all since it does not include the entire *sea* gene. Applicant has claimed specific primers and probes of about 20 or 21 bases in length from an entire *sea* gene having a length of 1443 bases.

Furthermore, the Borst sequences violate several of the primer set design guidelines that must be followed to obtain a set of primer and probe oligonucleotide sequences that will perform optimally in real-time fluorogenic PCR. Specifically, the two primers described in Borst are not suitable for use in identifying the *entA* gene by real-time fluorogenic PCR for several reasons, including: (a) the amplicon being of 272 base pairs while real-time fluorogenic PCR optimally requires 50-150 base pairs; (b) Borst does not teach the melting temperature of their primer pair, and primer pairs designed for optimal performance in real-time fluorogenic PCR have melting temperatures between 58 and 60 degrees C; and (c) the downstream primer sequence taught in Borst violates the guideline for primer selection that no more than two of the five bases at the 3' end of a primer be either G or C (Borst teaches a downstream primer with three G/C bases among the five bases at the 3' end of the primer).

Moreover, only one of the primers taught by Borst (that appearing in the text on p. 5423) binds a sequence inside the open reading frame encoding the SEA protein. The other primer binds a sequence upstream of the promoter for the *entA* gene. The use of this primer pair will fail to detect the gene if the gene has been excised from its native sequence and cloned behind a promoter that has been optimized for expression of the gene in another organism (as may be the case if the gene is used to create a genetically engineered biological weapon). Therefore, in addition to not being suitable for real-time PCR, the primers described on pages 5422 and 5423 do not constitute a functioning assay directed specifically and solely at sequences that encode staphylococcal enterotoxin A.

It should be noted that although the Office Action indicated no claims were allowed, no rejection was included to address pending Claim 16. Claim 16 is dependent from Claim 15 and is further limiting thereto since it includes as limitations the specific sequences for the

nucleic acid probe used in the method of Claim 15. Therefore, it is respectfully submitted that Claim 16 is also in condition for allowance.

In summary, Claims 15-16 remain in the case and based on the foregoing amendments and remarks should not be considered indefinite or obvious in view of the prior art cited. Accordingly, it is respectfully submitted that these claims are patentable and in condition for allowance. Early reconsideration and withdrawal of the rejections is earnestly solicited, as is allowance of the claimed subject matter.

Respectfully submitted,

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DATE

U. John Biffoni
Attorney for Applicant
Registration No. 39,908
Tel. No. (410) 436-1158